SEP 6 2002

510(k) Summary for 3DMed Co., Ltd. CalScoR

K021913

1. Submitter Name and Address

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REPUBLIC OF KOREA

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Date Prepared: June 10, 2002

2. Device Name

Proprietary Name: CalScoR Software
Common/Usual Name: Calcium scoring software
Classification Name: Picture archiving and communications system

3. Predicate Device

Accuview/AccuScore Software (K990241)

4. Intended Use

The CalScoR Software is intended to be used by a trained physician with the Rapidia software for the review and analysis of CT images as an aid in cardiac analysis.

5. Device Description

CalScoR is a Windows-compatible software program that runs with the previously cleared Rapidia Software (K012290). The Rapidia Software is a fast,

practical, and accurate tool for 3D (three dimensional) and 2D (two dimensional) viewing and manipulation of CT and MRI images using the most advanced graphics-rendering technology.

CalScoR can specify the location of calcium in images, calculate the calcium score based on Agaston's method display the percentile of the score with the graph, and issue reports.

6. Technological Characteristics

The CalScoR Software and the predicate device are both software programs that can be used for measuring calcium scores from CT images. The CalScoR software can be operated from a personal computer. The algorithm for calculating calcium score is based on Agaston's method.

7. Performance Testing

Tests were performed to compare the accuracy of the CalScoR's calcium score with that of the predicate device. A linear regression was used to demonstrate that the scores obtained from the AccuScore and CalScoR were similar. The slope was set to 1 and the intercept was set to 0. Additionally, an F-test was used to show that the two scores are essentially identical. The F-value of the experimental results was 13742853.39, which means that the two scores are identical within 0.0001(0.01%) error level

The testing demonstrated that the CalScoR performs all functions according to the functional requirements specified in the Software Requirements Specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

3DMed Co., Ltd.
% Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K021913
Trade/Device Name: CalScoR Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 10, 2002
Received: June 11, 2002

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K021913

Device Name: CalScoR Software

Indications for Use:

The CalScoR Software is intended to be used with the Rapidia software by a trained physician for the review and analysis of CT images as an aid in cardiac analysis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021913

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)